

**Opinion No 88 of 10. November 2025
about the communication of the carrier
status in the context of neonatal
screening in the Wallonia-Brussels
Federation**

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Belgian Advisory Committee on Bioethics

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Preliminary Warning:

The Committee's opinions are drafted in Dutch and French. Please consider these two language versions as official, even if translations in other languages are available.

Case request

On 24 April 2024, Bénédicte Linard, former Deputy Minister and Walloon Minister for Children, Health, Culture, the Media, and Women's Rights, contacted the Committee with a request for an opinion on the neonatal screening programme for congenital birth anomalies (see **Appendix 1**).

The request was expressed in the following terms:

'I hereby wish to request the advice of the Advisory Committee on Bioethics on a question with regard to the neonatal screening programme for congenital birth anomalies which has been arranged in the Wallonia-Brussels Federation. This has its basis on the one hand in the Decree of 17 July 2002 regarding the Birth and Early Childhood Agency and, on the other hand, in the Decree of 1 February 2024 regarding the processing of personal data as part of support missions, preventive medicine programmes, and parental support by the Birth and Early Childhood Agency. The Order of the Government of the French Community of 9 January 2020 regarding screening for congenital birth anomalies in the French Community defines the implementation methods of this programme.

The question at hand is finding out if there are cases of carriers of congenital birth anomalies who will not become ill and whether or not they should be informed of the situation.

As a matter of fact, carriers can have access to genetic counselling, but the aim of the programme is to identify sick people and treat them, rather than the implementation of genetic counselling.

At the moment, clinicians have different views on this subject, and that is why I am requesting the advice of your committee, in a context where the development of genetic screening increases the capacity to identify congenital anomalies.

So that you can address this issue, you will find enclosed a letter from O.N.E. and a note of the contextual setting.

Thanking you most sincerely in advance, Mr President, for the attention which you will give to this matter.'

Ms Bénédicte Linard, Deputy-President and Minister for Children, Health, Culture, the Media, and Women's Rights.

This request for an opinion was declared admissible at the plenary meeting of the Belgian Advisory Committee on Bioethics on 10 June 2024

1. Introduction

Neonatal screening, free of charge and routinely available, is for all newborn babies in Belgium regardless of their birth surrounds or their socio-economic situation. The programme is organised separately by the federated entities. It aims to identify at an early stage diseases which are serious, but treatable in order to prevent irreversible complications and ensure a better quality of life for the children concerned.

The programme was introduced in 1968 with screening for phenylketonuria via the Guthrie Test, but it has gradually extended to include other metabolic and endocrinal diseases¹. Nowadays, the programme in the Wallonia-Brussels Federation covers a group of 19 rare diseases, including congenital hypothyroidism, congenital adrenal hyperplasia, various forms of acidemia, enzyme deficiencies, mucoviscidosis, spinal muscular atrophy (SMA), and, since 1 January 2023, sickle cell anaemia.

The integration of sickle cell anaemia into the programme does reflect a step forward in terms of public health care, but it has brought to light some complex issues related to the communication of the results. Indeed, screening for this disease makes it possible not only to discover which children are affected, but also to identify children with sickle cell trait (heterozygotes) who generally show no symptoms. And so, this situation raises an ethical debate: What are the conditions under which it is necessary to inform parents that their child is a carrier of the disease? This questioning comes within a wider framework of the evaluation of the benefits, risks, and ethical implications of neonatal screening within both the Wallonia-Brussels Federation and Belgium as a whole.

In this context, the purpose of this advice is to examine the ethical, medical, and social implications of communicating the fact that a child is carrying sickle cell anaemia, all this within the framework of neonatal screening in the Wallonia-Brussels Federation. Although the main focus is on this condition, the reasoning set out could serve subsequently as a point of reference for other genetic disorders which are identifiable at birth, even in healthy babies.

¹ <https://www.depistageneonatal.be/depistage-danomalies-congenitales/pourquoi-depister/> (French only)

2. Definition of sickle cell syndromes

Sickle cell syndromes cover a series of hereditary diseases classified as ‘rare’ (with a prevalence of one to five out of 10,000 people) in Belgium². They affect haemoglobin, an essential protein for the transport of oxygen in the blood. These diseases are the result of gene mutations of the β -globin, leading to the production of an abnormal haemoglobin called haemoglobin S (HbS). The main forms are the sickle cell anaemia homozygous (HbSS) and the composite forms linking the mutation HbS to other abnormalities of the haemoglobin such as the haemoglobin C (HbSC) or the β -thalassemia (HbS β -thalassemia). In practice, the term ‘sickle cell anaemia’ often refers to all these syndromes.

These diseases are characterised in particular by the deformation of red blood cells. In the event of a lack of oxygen, dehydration, or infection, red blood cells containing HbS take on the shape of a sickle, and this disturbs their circulation in the blood vessels. That causes blockages (vaso-occlusive crises), accelerated destruction of red blood cells (haemolysis) and thereby a decline in their capacity to transport oxygen, and leads to chronic organ damage. Clinically, sickle cell syndromes can take the form of acute episodes of pain, chronic anaemia, and vulnerability to infections and serious complications, such as bone infarct, kidney damage, cerebrovascular accidents (AVC), and premature mortality.

Genetically, these syndromes spread in an autosomal recessive manner. To be affected by the disease, an individual has to inherit two mutated doses of the gene from the β -globin, namely one from each parent. Those who inherit only one dose are carriers of the sickle cell trait (heterozygotes). Although these carriers generally show no symptoms, they can pass on the mutation to their descendants.

Sickle cell anaemia occurs particularly frequently in regions affected in the past or present by malaria, especially Sub-Saharan Africa, the Middle East, India, the Mediterranean, and in certain

² <https://www.orpha.net/pdfs/data/patho/Pub/fr/Drepanocytose-FRfrPub125v01.pdf> (French only)

https://apps.who.int/gb/ebwha/pdf_files/wha59/a59_9-fr.pdf (French only)

https://www.cdc.gov/sickle-cell/media/files/factsheet_sickle_cell_trait-fr-508-a.pdf (French only)

https://www.pns.nl/sites/default/files/2020-04/2019%20Factsheet%20NHS_DEF_V2.pdf (in Dutch)

Mañú Pereira MDM, and others, Sickle cell disease landscape and challenges in the EU: the ERN-EuroBloodNet perspective. *Lancet Haematol.* 2023 Aug;10(8):e687-e694. doi: 10.1016/S2352-3026(23)00182-5. Epub 2023 Jul 11. PMID: 37451300.

Pinto VM, and others, Management of the Sickle Cell Trait: An Opinion by Expert Panel Members. *J Clin Med.* 2023 May 12;12(10):3441. doi: 10.3390/jcm12103441. PMID: 37240547; PMCID: PMC10219090.

A cross reference of the average number of births per year in Belgium (see STATBEL) and the prevalence of the disease (see depistageneonatal.be – French only) shows that this disease would affect about 40 to 50 births per year in Belgium. However, at the moment, it is not possible to estimate with certainty the number of children born each year as carriers, but this figure could well be higher than the number of children affected.

regions of the Americas (e.g. the Caribbean, Brazil, etc.). This link is explained by the fact that the sickle cell trait imparts partial protection from malaria. In Belgium, the presence of the disease is linked mainly to immigration from those zones. Its estimated prevalence is approximately one person in 25,000, although there is no official data on the origin of the people affected.

Health effects for carriers of the disease

Unlike people who suffer from homozygous forms of sickle cell syndrome (HbSS), carriers do not exhibit sickle cell disease under normal conditions and they do not develop the severe form of the disease. However, this status can have health consequences in extreme circumstances.

Renal abnormalities such as proteinuria, haematuria (the presence of blood in the urine), or a chronic renal failure, which require a dialysis or a transplant, are more frequent in carriers than in the population as a whole; renal medullary carcinoma affects carriers of sickle cell anaemia almost exclusively. Furthermore, carriers present a moderately higher risk of deep vein thrombosis and pulmonary embolism, as well as neurocognitive disorders related to subclinical AVCs, more so than non-carriers. There are also reports of more cases of rhabdomyolysis and associated sudden death amongst sickle cell trait (HbAS) athletes.

Extreme circumstances, such as acute and/or prolonged hypoxia (a drop in oxygen), severe dehydration, suboptimal blood circulation, and acidosis (pH low blood sodium), increase the risk of complications. Carriers are particularly susceptible on trips at altitude, during severe physical exertion, or under general anaesthetic for major surgical procedures, and this necessitates precautionary measures. Changes in lifestyle, increased vigilance, supervision in the presence of additional risk factors (including during pregnancy), and adequate hydration and regular breaks for top-level athletes are recommended for carriers.

Health care providers, in particular anaesthetists, should also be informed of the carrier status with a view to modifying the treatment (hydration, oxygenation, etc.) and acknowledging possible complications at an earlier stage.

This need for modification is not limited solely to the context of a medical operation. Therefore, certain everyday clinical situations, such as the prescription of iron for women with anaemia, can also be directly affected by lack of awareness of the carrier status. In the case of sickle cell trait (AS), an iron supplement might not only turn out to be useless, but also it can be potentially toxic, especially if the ferritin count is already high. Moreover, this example also applies to children and men. Therefore, the integration of this information into the medical file where it is available would help to prevent medical errors and enhance the clinical relevance of medical decisions.

3.The state of play in neonatal screening in the Wallonia-Brussels Federation

Neonatal screening is a public health programme available for all newborn babies in Wallonia-Brussels Federation (WBF), whether the child is born in a hospital setting or at home³. Free access to this screening guarantees equal opportunities for all children, regardless of their socio-economic or cultural background.

The procedure is generally conducted between 48 and 96 hours after the birth, a crucial moment which makes it possible to detect serious medical conditions at an early stage before the symptoms become irreversible. The test can be carried out in a maternity unit or at home by a midwife. In practical terms, it consists of extracting a few drops of blood from a vein on the hand of the newborn baby. These samples are collected on blotting paper labelled with the child's name and then sent to a certified laboratory for analysis.

It is important to note that this test, which ought to be subject to a process of reporting and informed consent, is currently still very rare. Despite initiatives like sites devoted to neonatal screenings and flyers supplied to maternity units, both the screening centres and the ONE (Birth and Children's Office) acknowledge that the work on information from teams and parents is still insufficient in general terms. In Wallonia, the principle is based on an 'opting out system', that is to say that the sampling is completed unless there is explicit opposition from parents. By contrast, in Flanders it is a question of 'opting in', albeit to a lesser degree, meaning that parental consent has to be obtained. However, it is important to note that the professionals who are responsible for the sampling (mainly midwives and nurses) are not trained to give detailed explanations on the diseases for which the babies are screened.

The screening programme in the WBF currently includes 19 rare diseases, which are divided into four categories: metabolic disorders (e.g. metabolic disorders, phenylketonuria, leucinos, and certain organic acidemias), endocrinal diseases (such as congenital hypothyroidism or congenital adrenal hyperplasia), and certain diseases which can be identified by molecular tests like mucoviscidosis, spinal muscular atrophy (SMA), and, since January 2023, sickle cell anaemia. Although these diseases are classified according to their physiopathological mechanism, most of them have a genetic origin, whether it is a question of mutations affecting enzymes, hormone receptors, or other essential biological functions.

³ <https://www.depistageonatal.be/depistage-danomalies-congenitales/en-pratique/> (French only)

These diseases have been selected on the basis of criteria of the severity, availability of treatment at an early stage, and effectiveness of screening tests.

In theory⁴, the communication of neonatal screening results follows a clear pattern: If no targeted disease is detected, the parents do not receive any feedback; by contrast, in the case of a positive test result, the parents are contacted within 15 days in order to start some further tests and, if necessary, immediate specialist care.

In practice, this framework is generally true, but several nuances should be added. When no disease is detected, the parents certainly do not receive any direct information; however, the results are only available after a period of one to two months, and they are conveyed to maternity units solely in the form of a monthly list. This mechanism therefore excludes individual feedback unless the parents ask for it explicitly. If the result cannot be interpreted or the sample is non-compliant (a situation not provided for explicitly by the notional protocol), a second sample is required without any treatment being involved at this stage. The contact with the parents therefore depends strongly on the practices of each maternity unit: Some of them prefer mail delivery, others make contact by telephone, with or without voice messages or follow-up, and this leads to a diversity of approach which is poorly aligned with the screening centres. Finally, in the case of an abnormal result which necessitates a referral, the protocol is applied with precision: The maternity unit makes contact by telephone without delay, with the support of the reference centre if necessary, and sends reminders until the link with the parents is confirmed in order to ensure continuity of care⁵.

In the Wallonia-Brussels Federation the neonatal screening programme is based on a co-ordinated and decentralised organisation involving several certified laboratories supervised by the health authorities. This organisation does spread the workload, but it also requires close collaboration between the laboratories, hospitals, general practitioners, and the specialist services responsible for following up families.

The Birth and Early Childhood Agency (ONE) plays a leading part in this system: It co-ordinates the programme, distributes information to the families, and trains health care professionals in order to ensure clear and empathic communication. The ONE also takes part in the ongoing adaptation of the programme in line with scientific advances. The recent integration of sickle cell anaemia into the panel of detected diseases illustrates this dynamic progression, whilst highlighting new logistical and ethical challenges.

⁴ <https://www.depistageneonatal.be/> (French only)

⁵ Testimony of the Director of the Paediatric Laboratory and the neonatal screening centre of the Lionel Marcellis Free University of Brussels.

However, according to the experts who were interviewed, there are still several organisational challenges. The follow-up after the screening is sometimes inadequate, especially for vulnerable people who face linguistic, cultural, or economic barriers. Moreover, there are still communal disparities with regard to quality support, access to centres of expertise, and alignment of detected diseases. These differences jeopardise the fairness of the system and a good understanding of the information by families.

The extension of the programme to include new diseases like sickle cell anaemia increases the strain on human and material resources. This necessitates the recruitment of qualified staff, investment in suitable infrastructure, and precise data management, especially for its integration into digital medical files.

In view of the initial purpose of the Guthrie test, namely the detection of children affected by diseases, the implemented mechanisms do not aim to identify carriers. Moreover, most of the tests used increase the immunobiochemistry. The introduction of genetic tests, which were designed initially to confirm abnormal results or to detect new diseases such as sickle cell anaemia, also makes it possible to identify carriers, thereby raising an unprecedented challenge linked to the communication of this status.

Up until now, in the WBF, this information has not been conveyed for detected diseases⁶. Users' representatives have stressed that if screening for sickle cell anaemia leads to such a communication, that could create a precedent and lead to a generalisation of this practice towards other diseases, thereby raising ethical and organisational issues.

And so, neonatal screening in the WBF forms an essential programme which is constantly developing. Its deployment raises questions of coherence, follow-up, resources, and fairness. These elements call for ongoing reflection on its objectives, application conditions, and limits.

⁶ At present, the communication of the carrier status for mucoviscidosis is not consistent in the Wallonia-Brussels Federation, unlike in other countries like the United Kingdom, which integrates this dimension into its screening policy.

<https://www.gov.uk/government/publications/screening-tests-for-you-and-your-baby/4911c84d-4393-4174-a15a-52db192bec62#resultats-possibles>

4. The legal framework

The law on information on the carrier status falls within a wider framework of patients' rights, which are defined by Belgian legislation. Article 7 of the Law on Patients' Rights stipulates that any person has the right to full disclosure of information regarding his or her health and its likely development. This information must be communicated in an appropriate manner, in a comprehensible language, and within a period which is appropriate to the patient's circumstances. A strict application of the law could therefore imply that this comprehensive information includes the data from the neonatal screening, including the results relating to carrier status.

However, this same article provides for two important exceptions: On the one hand, there is the right not to know, namely the option for a patient to choose not to receive certain information with regard to his or her health. It should be stressed that, despite the nuances and limits which are specific to this legal framework, the Committee considered it appropriate to mention this exception precisely because in practice this framework has been invoked by patients or patient associations. Even if this invocation by parents has strict limits from a legal and ethical point of view, it expresses ramifications and major fears of social, cultural, and communal discrimination which such information can carry both for the child and his or her parents and their family. Furthermore, we must draw a distinction between the right not to know, which is based on a conscious decision by the patient or his or her agents, and the non-communication of information, which assumes that data does exist, but it has not been made accessible. This latter case raises specific questions about the responsibility of institutions and professionals to ensure ethical traceability of this data over time.

On the other hand, the second exception to the communication of information concerns the therapeutic exception. This authorises a health professional to defer or restrict the communication of information provided that to do otherwise might harm the patient severely and provided that a second health professional has been consulted on this matter. This action acquires real meaning in situations where the disclosure of a diagnosis or a carrier status raises particularly sensitive psycho-social issues such as, for example, in the case where the disclosure of a carrier status reveals a possible mismatch between the child and the presumed father. In such circumstances, the care is not limited to the act of telling, but finds itself in a complex temporality. Progressivity then becomes a guiding principle: It is not a question of withholding information relevant to the child's health, but making sure that its communication is structured, suitable for the context, and integrated into a progressive framework, which protects all the people concerned. This framework implies ongoing evaluation of the priority of the information to be communicated, taking account simultaneously of the best interests

of the child, the family dynamics at stake, and the appropriate time so that this information can actually support a course of treatment and the relationship.

Indeed, concerning the child himself or herself, the exercise of underage patients' rights is framed in Article 12 of the Law on Patients' Rights. This specifies that the parents (or legal guardians) exercise the patient's rights until the child is capable of exercising them himself or herself. In the framework of neonatal screening, that means that decisions with regard to the access to certain information, such as carrier status, lie initially with the parents. However, it is still necessary for them to be informed in advance of the existence of this information and the option of having access to it. If that is not the case, the right to information remains theoretical and it is not possible to exercise parental autonomy clearly or effectively. However, this decision-making power must be exercised in keeping with the interests of the child and by maintaining his or her ability to decide for himself or herself. Temporality and the importance of communication then become key issues⁷.

The gradual empowerment of the underage child with regard to access to information is now recognised in Belgian law. Depending on his or her maturity and powers of comprehension, a child can gradually exercise his or her own choices with regard to information or non-information.

Finally, reaching the age of adulthood marks a key moment in the full and comprehensive exercise of these rights. Once an individual reaches the age of adulthood, he or she has the right to access all his or her medical data. If his or her carrier status has not been communicated to him or her during childhood, he or she must have the option of finding this out on reaching the age of adulthood, if this information is available in his or her medical file. This implies that the health care system stores this data in a manner which makes it accessible, in keeping with the law on information, and allows each person to exercise a clear choice at every stage of life.

For its part, the General Data Protection Regulation (GDPR) also puts down some legislative markers. Within the neonatal screening framework, the data relating to the carrier status constitutes sensitive data which pertains to the categories of both health and genetic data, as specified in Article 9 of the GDPR. Processing this data is in principle forbidden, except in certain limited cases, in particular if it is based on explicit consent, pursues medical or public

⁷ In the context of patient rights to the information and to inspect the file, it is also necessary to take into account the potential role of the person of trust, as defined by the law on patient rights. This person, who can be appointed by the parents or by the patient himself or herself if he or she is old enough to do so, can be a treating physician. He or she is therefore empowered to receive information, formulate opinions, help with the mediation between the interests of the child, those of the parents, and the care demands. His or her role can turn out to be particularly relevant in situations where the communication of certain information such as the carrier status raises major ethical or emotional pressures.

health purposes, or is registered in a programme of research with appropriate safeguards. The collection, storage, and communication of this information must therefore be strictly justified, limited to what is necessary, and regulated by specific measures relating to security, traceability, and documentation.

According to Articles 12 to 15 of the GDPR, any person concerned (or his or her legal agent) must be informed in a clear and accessible manner of the existence of data processing, its objectives, the nature of the data collected, the length of time for which the data will be stored, and the rights related to it. If a carrier status is detected and stored, it becomes data to which the parents can have access until their child becomes a legal adult, and to which the child himself or herself can have access once he or she becomes a legal adult. The right of access is inseparable from the right to information, unless the data has not been stored or integrated into a filing system.

Finally, Article 23 of the GDPR authorises member states to restrict certain rights provided for in Articles 12 to 15, especially on grounds related to public health, security, or the protection of the rights of others. However, such a restriction must be provided for by specific national legislation, justified by an important general interest, proportionate, and accompanied by adequate safeguards. Within the context of neonatal screening, the decision not to communicate information such as carrier status, however the information is produced and stored, would therefore have to be based on an explicit legal foundation and respect these strict conditions. In the absence of such provisions, silence or the withholding of information could form a breach of the European legislative framework.

5. Ethical considerations

The ethical debate surrounding the communication of carrier status in the context of neonatal screening for sickle cell anaemia highlights a series of fundamental tensions between the individual rights and the psycho-social issues of families on the one hand and, on the other hand, the objectives of public health and the organisational capacities of the health care system. This is part of a wider issue: In a democratic society equipped with advanced medical and technological resources, how do we take on the implications of widespread screening which, whilst targeting a specific disease, can also reveal genetic information which is said to be ‘associated’, such as carrier status?

The storage, transmission, and utilisation of this data call for separate ethical reflection. Data can be available without it necessarily being appropriate to communicate it in all situations or to all contact persons involved. And so, there is a need to consider the real purposes of the storage: Is it helpful to the child’s immediate health needs? To the child’s future choices? To those of the child’s parents? To preventive family health care? Or to public health purposes in the population as a whole? This distinction is essential to avoid a purely technical approach to the data, which gives priority to the sense of transparency over that of care or justice. The voluntary non-communication of available data, in the absence of explicit justification, could be perceived as a violation of the principle of transparency, but it could also raise an ethical choice based on the protection of the child or respect for the temporality of the access. Furthermore, if the right not to know is recognised, this implies a clear request which cannot be assumed by default or mistaken for an absence of information or a structural retention of data.

Within the context of neonatal screening, the principles of the right to information, the right not to know, and the therapeutic exception raise major ethical and practical issues. Parents must receive clear, intelligible, and adequate information which does not result in disproportionate stress or lead to hasty decisions. Nevertheless, this prudence in communication should not conceal a fundamental question: Beyond the pathological findings which justify immediate medical care, does some data (such as the carrier status) highlight the newborn child’s state of health in the sense that it should be communicated consistently? This question fosters reflection on the very nature of the genetic information, its medical and ethical status, and on the co-related rights of the family (and, over time, of the child) to access some relevant elements for their present or future health.

Access to this information therefore not only constitutes the letter of patient rights. It blends with the spirit of those rights and paves the way for programs of specific health care for both sick children and carriers with no symptoms by making it possible to predict vulnerabilities, adapt medical follow-up, or advocate for expanded family screening. In a context of targeted

therapeutic approaches (for example CRISPR Case9), this delayed accessibility makes perfect sense. Finally, progressiveness reveals all the more so that some discoveries can have sensitive family implications and necessitate a framework of gradual, prudent, and respectful care.

From this perspective, the notion of progressive information becomes a key ethical benchmark. It makes it possible to adapt the temporality of the communication to the psychological, social, and cultural realities of the family, while ensuring that the child (or the health professionals who help the child) can have access to it at clinical or personally significant times (parental plans, initial symptoms, adulthood, treatment, etc.). This approach implies safe storage of the information, its explicit integration into the medical file, and a document structure making it possible to delay activation without loss of access or disruption to the continuity of the care. And so, it could also help to align practices between centres so that the right of access does not depend on the location where the child receives care.

5.1. The interests of the child

The interests of the child constitute a fundamental principle, but the interpretation thereof in the context of neonatal genetic screening (especially concerning the communication of carrier status) requires an intensified ethical alertness. This principle implies in particular the acknowledgement of the 'right to an open future', that is to say respect for the child's future ability to make his or her own choices without being conditioned by genetic information at an early stage. In the ethical view of the 'right to an open future', according to J. Feinberg, the premature communication of sensitive information, even involuntarily, can permanently affect identity building, parental attitudes towards the child, the medical journey, or the child's future decisions on his or her own reproductive health.

Moreover, access to this same information can turn out to be crucial to the autonomous and clear exercise of choice with regard to health, reproduction, or more extensively a lifelong project. A delay in communication could deprive the child, when he or she reaches adulthood, of helpful elements to prevent certain risks or to consider his or her parenthood by having relevant health information to hand. As a consequence, there is an ethical and structural tension between two equally legitimate principles: on the one hand, respect for the right not to know and the protection of an open future; on the other hand, acknowledgement of the right to genetic information, considered as a lever of autonomy and future emancipation.

These issues reveal that the concept of the interests of the child is not unequivocal and that it cannot be deemed as self-explanatory. Depending on the context, to inform or not to inform can be interpreted in turns as relevant to the interests of the child or, on the contrary, as a tool to achieve other purposes above all else: those of the parents, of health professionals, or of the health system. The basic question which is raised by the Committee in this respect could

be formulated as follows: Who is responsible for this information and who is responsible for transmitting it? In other words, is this about information which benefits the child or is it a process by means of which the responsible adults endeavor in advance to prevent or direct choices which they believe to be appropriate for the child?

The deliberations of the Committee have brought to light the evolving and contextual nature of the question of the transmission of information relating to carrier status. The response to this question does not depend solely on the age or maturity of the child, but also on terms and conditions and the moment chosen to transmit the information. Genetic data can be produced and stored without being communicated immediately; its communication can be planned gradually, delayed, or contextualised to key moments in life: occurrence of symptoms, reproduction, adulthood, or a medical operation. This temporality of information must also take account of particular situations such as early or unwanted pregnancies, which can lead to the acknowledgement of the genetic status and necessitate an individual approach.

When parents choose not to be informed of their child's carrier status, it seems necessary to put a system in place to allow them to delay communication while ensuring that this information is still accessible later on at a time which is relevant to the child's health or life choices. Such an approach implies the secure storage of the information, its future accessibility for health professionals or for the child himself or herself, and a suitable institutional arrangement. The structure of the medical file could be mobilised for this purpose under the proviso of respect for the 'right not to know' and the right of access to health data. However, this mechanism raises ethical questions of a clinical nature (relevance of a planned medical follow-up), a family nature (the role of siblings in expanded screening), and an organisational nature (variability of practices between centers, the shortage of general practitioners). From this perspective, a progressive approach does not aim to impose the communication of genetic information, but to ensure that it can be transmitted subsequently under conditions which respect autonomy, the best interests of the child, and clinical relevance. Ultimately, it is not a question of deciding abstractly between two opposed principles, but acknowledging that their articulation should be the subject of an ethical, informed, contextualised, and evolutionary construction which is adapted to the specific framework of neonatal screening on a scale involving the whole population. This work is based on a fruitful tensioning operation between the rights of the child, the responsibility of adults, and institutional capacities to accompany these transitions in a coherent and sustainable manner.

5.2. The interests of the parents

The interests of the parents in the context of neonatal screening unfold through their legal and ethical responsibility to ensure the well-being of their underage child. As temporary agents

of the child's rights, they are called upon to make clear decisions, something which implies access to relevant, comprehensible, and contextualised information. For this reason, their knowledge of the carrier status can be a lever of anticipation and adaptation: It encourages greater vigilance in the medical follow-up of the child and, if the need arises, of the parents themselves, fosters deep reflection on future reproduction, and can lead to broader screening within the family (parents, siblings, or other close family members)⁸.

However, this valuable potential cannot conceal the ethical ambivalences which it creates. If such information can help to uphold parents in their supporting role, it can also have an effect on them as people, regardless of the child. It can create anxiety, revive tensions within the family, or even fuel cultural and stigmatising depictions of genetic diseases. Therefore, the distinction between the usefulness of the information to take care of the child and any psychological, social, or cultural repercussions from that same information on the parents themselves should be set out explicitly and taken into account in any ethical reflection relating to the transmission of carrier status.

The deliberations of the Committee emphasise that the risks of confusion (between carrier and disease, between prognosis and certainty) are real. Information, even if correct, can be poorly interpreted or taken badly if it is not supported in an appropriate manner. That necessitates a gradual transmission which is mindful of cultural, social, and family vulnerabilities. The key issue, therefore, is not solely the fact of informing, but also doing it in such a way as to provide real support for the parents' ability to act in the interests of their child, whilst safeguarding them from excessive emotional burdens or avoidable guilt.

In this respect, the interests of the parents should be considered in all their complexity: both as a vehicle of care towards the child and as a full human reality, affected by the content, the time, and the terms and conditions of the transmitted information. These interests also include a legitimate need for comprehension, justifying the access to appropriate genetic advice, not only to clarify the implications of the carrier status, but also to help with questioning regarding reproductive and family issues which is likely to ensue. Such an approach would help to reduce erroneous interpretations and reinforce the family's trust in the screening process.

⁸ Indeed, it might be relevant to add that this wider screening scale (potentially involving other family members) necessitates appropriate information from the parents in advance. In particular, this means raising their awareness of the possibility of family screening by presenting the scientific evidence of genetic transmission and explaining what does and does not reveal the carrier status in their child. This approach would encourage clear comprehension of medical, genetic, and reproductive issues, whilst preventing misunderstandings or erroneous interpretations which are likely to result in needless anxiety or poor decisions.

5.3. The interests of society and public health policies

The interests of society and public health policies manifest themselves nowadays in the far-reaching changes which are transforming the integration of genetics within health care. Technological advances in neonatal screening, combined with growing accessibility to genetic tests amongst the general public, are driving the emergence of new collective responsibilities with regard to the production, storage, and recovery of genetic data. In this context, the carrier status (and on a broader level information referred to as associated or incidental information) constitutes a key factor, which compels us to rethink the conditions for genetic education amongst the general public, transparency in proportion to the complexity of the issues, governance in line with the principles of the right to information, justice, and fairness.

Advice no. 76 of the Belgian Advisory Committee on Bioethics relating to non-invasive prenatal testing (NIPT) and sexual aneuploidies, provides a reflection which can be transposed to neonatal screening. It is recommended to treat incidental data according to three criteria: medical relevance, usefulness to the patient or his or her family, and social and ethical acceptability. The advice calls for a graduated support and communication framework which respects the rights of the patient and individual temporalities and for institutional foresight of their management via clear conditions of consent, deferred storage, and dialogue between disciplines.

Furthermore, the impacts of carrier status vary in accordance with the diseases. In the case of sickle cell anaemia treated in this advice, this information covers an immediate effect for the child's health because it can direct therapeutic decisions, whereas in the other cases the information mainly concerns the risks of genetic transmission and reproductive choices. This heterogeneity imposes a detailed assessment for each disease of the clinical, preventive, or ethical relevance of sharing the information. It also calls for clarification of the respective roles of the neonatal screening programme, preconceptional screening, general practice, and genetic advice in the management of this data. Without having to take on everything, neonatal screening should nevertheless anticipate the emergence of such information and provide a coherent guide on adequate resources.

From this perspective, advice no. 58 of the Belgian Advisory Committee on Bioethics (27 January 2014) concerning the funding of expensive medication provides a useful framework for analysis. It draws a distinction between formal criteria (transparency, recourse, and rational justification) and content criteria (fairness, efficiency, cost-benefit ratio, and usefulness for the patient). This approach can inspire decisions concerning integration, new tests, and recovery policies for the genetic information.

The non-communication of available information for the sole reason that it is complex or of an alarming nature is not sufficient to disqualify it. Such withholding could be perceived as unjustified, even as a breach of patient rights and the principles of personal data protection. This observation is particularly alarming in a national context marked by a heterogeneity of regional policies, a lack of alignment of facilities for archiving, recalling, and gradual access to genetic information, and highly variable practices between the screening centers.

With due regard for the initial aim of the Guthrie Test (namely the early detection of children affected by diseases), the system put in place was not designed to identify carrier status. Genetic tests, which also make it possible to detect carriers, were used originally only to confirm abnormal results.

It should be noted that in Belgium prevention in the framework of health care falls within community authority. This means that reporting policy on carrier status can vary between regions.

Nevertheless, field data shows high variability regarding the manner in which parents react to this information or request genetics assistance (or otherwise).

With prevention coming under community authority, neonatal screening therefore creates specific disparities between the federal entities both in access to information and in family care. These differences are not limited solely to the carrier status, but include the whole system: composition of panels, clinical protocols, terms and conditions of communication, and support facilities. They manifest themselves as between federal entities and between centers and medical teams. The screening panel, the communication criteria, and the quality of follow-up vary depending on the location, exposing families to a form of injustice based on location.

A national alignment is gaining a foothold, not as a rigid uniformity, but as ensuring coherence in public health policies in accordance with shared principles. Such an alignment should include screening panels, terms and conditions of storage and recovery of information, and the support process. Otherwise, access to certain data is still determined by the place of birth, consultation, or follow-up, with a risk of reinforcing social inequalities in health care. These observations ask for clarification of our collective purposes: Is it a matter of protecting the child from premature information and guaranteeing him or her gradual and clear access to his or her data from a perspective of autonomy and empowerment?

Certain diseases like sickle cell anaemia pose specific questions: Does carrier status justify an early medical follow-up? If so, the question raises not only the issue of the right to information, but also the clinical relevance of the action. This debate highlights the necessity of defining **national policy**, **clinical protocol**, and **communication protocol** as three

interdependent aspects in a framework of ethical and pragmatic governance. Any development in that sense must be implemented in an **intercommunity dialogue** with respect for existing institutions.

Finally, communicating carrier status transforms the health care system organisation. It means:

- The targeted training of professionals for the announcement of genetic results;
- The strengthening of genetic advisory branches;
- The production of information support which is culturally and linguistically appropriate;
- And the implementation of secure systems for the storage and delayed transmission of information which can be activated at key moments in life.

These technical demands also require the addition of psychological, social, and cultural support which is essential in order to avoid the harmful effects of information which is poorly understood or stigmatising. Finally, wider screening for new diseases calls for reflection on the sustainability of the system: Without adequate investment there is a risk of a multi-speed system emerging where the most fragile families, as a result of intersectionality, would be the least able to enjoy the promises of genomic medicine.

5.4. Ethical principles in tension

The discussions at Committee level, as explained by expert reports, study of the subject literature, and completed interviews, have made it possible to expose a whole range of ethically complex issues, which span the different levels of interests at stake: those of the child, the parents, professionals, and society in general. These tensions cannot be addressed unequivocally and call for a balanced analysis which is sensitive to the various family situations and care trajectories.

Respect for the child's informational self-determination constitutes an initial basic requirement. This is founded on a gradual recognition of the child's ability to understand, pass judgements, and make decisions in accordance with his or her level of maturity and cognitive and emotional development. As a consequence, all transmission of non-urgent genetic information such as carrier status should be delayed, framed, and made accessible at a time when the child reaches adolescence or adulthood and is able to receive it with sufficient discernment. The exercise of the child's rights also involves scrupulous organisation of future terms and conditions of access to the information so as to accommodate the right of access to information and the 'right to an open future'.

Reproductive autonomy (both of the parents and the child in the future) constitutes another key aspect, but it is controversial. On the one hand, access to information makes it possible to think ahead and make enlightened choices on medical care and family issues; on the other

hand, it can inadvertently restrict the child's future by freezing certain horizons or identities. This dilemma goes to the heart of the right to an open future, taken as meaning the option of not confining an individual to a trajectory set out in advance. It calls for an appropriate temporality of information and support structures which allow families to face choices without haste or pre-determination.

The right to information confronts the right not to know, which is recognised both by Belgian law and European legislation. Some families want to be informed at an early stage in order to prepare better, whilst others prefer to disregard data which could create needless anxiety or misunderstandings. Neither point of view is inherently better than the other one, and that is why terms and conditions of information should be able to reflect and respect the preferences of the people concerned. The way in which information is presented (not imposed) is a decisive factor here. However, this right not to know can encounter limits when the absence of information poses a palpable risk to the health or life of the person concerned. In the case of a carrier of sickle cell anaemia, for example, certain complications can be avoided by medical follow-up at an early stage; the ethical balance between respect for the desire not to know and urgent preventive care should therefore be the subject of a rigorous contextual assessment. Indeed, the denial of the initial information relating to the disease or the carrier status could also restrict future access to essential information such as that on the emergence of new and effective treatments from gene therapy.

Finally, we should not lose sight of the fact that the lack of communication does not in itself constitute the exercise of not knowing.

Respect for psychological, social, and cultural vulnerabilities involves a particular responsibility to contextualise the information transmitted. Faiths, family representations, migratory stories, or previous experiences of stigmatisation deeply affect the receipt of all genetic data. An ethical approach cannot be satisfied with a universalist logic. It has to integrate the diversity of life experience with the need for cultural and relation-sensitive mediation.

The question of the balance between individual interest and family or collective implications also constitutes a source of tension. The sharing of genetic information can make it possible for other family members (brothers, sisters, parents, etc.) to be screened or to think ahead about certain decisions. However, it can also rekindle conflicts, produce exclusionary effects, or create unsolicited suspense. The circulation of the information must not be regarded as a good thing in itself, but as a process with effects which have to be carefully supported.

Structurally, distributive justice dictates that everyone can fairly access information, support, and the necessary resources to understand genetic screening issues and take advantage of them. That is not limited to the assurance of a technical offer which is identical for everyone:

It is still necessary for each person to have a real opportunity to benefit from it. Therefore, it is important to identify and rectify inequalities which can impede access, whether they are economic, geographical, linguistic, educational, or cultural in nature. Failing that, there is a risk that only better informed or better supported individuals can take full advantage of these systems to the detriment of those who are more vulnerable. Finally, the principle of non-maleficence underlines that good intentions which are poorly deployed can produce harmful effects. Anguish, guilt, introspection, even the rejection of the child, or family pressures on them at the time when he or she is old enough to reproduce can ensue from poor communication. It will not suffice to act with a praiseworthy purpose. It is necessary to anticipate the effects of each action and integrate into each step of the screening process a constant ethical vigilance which is proportional and appropriate for the people concerned.

5.5. Recommendations and ethical summary

In the light of the findings, the Committee proposes to recognise a right of access to the information relating to the carrier status in the context of neonatal screening for sickle cell anaemia without creating an obligation to provide automatic communication. Such a recommendation is based on a respectful co-ordination between the right to information and the right not to know, two principles also recognised in the area of fundamental rights and clear consent. It is still necessary, however, for people to be informed first of all of the existence of this data and the option to have access to it. A person cannot refuse to acknowledge this if he or she is aware that the information exists. And so, it is not a matter of imposing awareness, but guaranteeing real and enlightened freedom of choice (for the child and his or her parents), without adapting this approach to the diversity of clinical, family, and cultural situations. For this right to be exercised clearly and gradually, the Committee recommends developing terms and conditions of delayed communication, taking account of the child's maturity, family dynamics, and social or cultural vulnerabilities. That does not exclude the possibility for the parents to access it immediately if they so request and if this communication is considered relevant in the interests of the child. This gradual approach involves careful support from trained professionals, the utilisation of multilingual and pedagogical information materials and enhanced access to mediation and genetic advice. It is a matter here of positioning the bases of an ethical framework of anticipated consent in which families would be informed in advance of different pieces of information which genetic tests could create, and they would have the option of expressing their preferences regarding the receipt of this data.

With this in mind, the Committee also recommends the introduction of secure systems for storing genetic information. These systems should allow access later (for example, when the child reaches adolescence, the entrance into adulthood, or in the context of reproductive choices), whilst ensuring confidentiality, traceability, and the option of personalised support

at each stage of consultation. Such infrastructure would enhance the future autonomy of individuals, whilst respecting the unique temporality of their personal development.

Aware of current disparities between communes, centers and diseases, the Committee calls for a national alignment of information practices on the communication of carrier status. This alignment should guarantee screening for the same diseases and fair access to information for both neonatology and gynaecology without denying the contextual adjustments which are necessary to take account of local realities. It could rely on communal principles (transparency, progressiveness, and support), whilst respecting the diversity of experiences and clinical approaches.

In addition to these recommendations, the Committee insists on the importance of a systematic evaluation of the purpose and recipients of genetic information. The fundamental question to ask is as follows: Who benefits from the transmitted information? Is it intended for the child because it is relevant to his or her health or reproductive future? Or for the parents, to help them take better care of their child or reflect on their own parenting? Or for professionals, to help them respond to a medical, legal, or deontological demand? This clarification is essential for directing communication decisions and ensuring that they are justified by a real, proportional, and contextualised benefit. This plays a full part in an ethical framework of consent and the transmission of sensitive information.

Finally, the Committee thinks that this specific reflection should be part of a wider vision on the future of genetic neonatal screening. The anticipation of technological changes, ongoing training of professionals, raising of public awareness, and progressive clarification of the legal framework are the levers to construct public health care policy which is coherent, ethical, and sustainable.

In conclusion, the communication of carrier status cannot be reduced to a simple transmission of information. It accepts a collective responsibility i.e. that of recognising the information as a form of care, transparency as an ethical duty conditioned by respect, and the diversity of human situations as a resource to be supported. For this reason, it calls for a shared policy, which is founded on fundamental rights, attentive to vulnerabilities, and open to forthcoming changes.

6. Conclusions

Following an in-depth analysis conducted within the framework of this referral, the Advisory Committee on Bioethics would like to emphasise that the question of the transmission of carrier status in the context of neonatal screening for sickle cell anaemia cannot be reduced to a simple balance between benefits and risks or to a binary opposition between knowing and

not knowing. It commits to a wider reflection on the meaning of care, the right to information, ethical obligations towards children and their families, and collective responsibilities with regard to public health care.

The Committee recognises that carrier status does not per se constitute a disease. However, in certain medical, extreme, or specific circumstances (intense physical effort, hypoxia, anaesthesia, etc.), it can have serious consequences for the individual person's health. Furthermore, this status takes on major importance for the family's preventive efforts and reproductive plans. For this reason it constitutes a potentially useful health detail, sometimes precious, for patient support in the future.

However, this information cannot be communicated without discernment. This requires appropriate arrangements which respect the right not to know, the underage child's gradual autonomy, and the social, psychological, and cultural realities of each family. The Committee particularly wishes to draw attention to the risk of stigmatisation, confusion between carriage and disease, emotional overload for the parents, or even violation of the child's right to build his or her own open future at a later stage in life. The Committee stresses that these elements strengthen the need for gradual, contextualised, and supported communication.

From this perspective it is essential to repeat that genetic information management (its creation, storage, perusal, or transmission) cannot be divorced from the initial information and consent procedure. Any subsequent communication strategy is based on decisions made at the time of consent before the test is conducted. Therefore, it is necessary to anticipate from this step onwards the future implications of genetic data which could be produced in such a way as to allow families to formulate free and enlightened choices on information which they do or do not wish to receive.

The Committee's reflection goes beyond the sole instance of sickle cell anaemia. In reality, this situation constitutes a revelation of broader issues which will emerge with the accelerated development of technology for neonatal screening and genetic screening on a wider scale. In the near future, screening could be carried out simultaneously for several hundreds of genetic conditions. This development calls for far-reaching adjustments of facilities for information, guidance, training for professionals, and support for families. The Committee insists on the need as of now to develop an ethical and technological infrastructure to meet these transformations: secure storage of data, entry in the medical files, delayed access to information at certain key moments in life, support from experts in genetics, and suitable and culturally adequate psychological support.

Accordingly, the Committee recommends that carrier status should be recognised as information to which families can have access as part of their rights and not as data to be transmitted automatically and routinely. This right to information should be marked by well

defined procedures which are based on respect for individual preferences and high-quality humane treatment. That involves institutional investment in tools, human resources, and the necessary training to maintain an ethical and sustainable public policy. An alignment of practices between communities is also indispensable to ensure fair access and prevent differences in treatment reinforcing social or regional inequality.

Finally, the Committee wishes to draw the attention of political authorities to the importance of a long-term vision. The issue here goes beyond the simple transmission of a medical result. It affects the way in which a society provides care, respect for autonomy, and the protection of individual freedoms in a world where technology is constantly producing more and more complex and sensitive data. Meeting these challenges requires clear choices, collective commitment, and coherent mobilisation between disciplines with principles of transparency, fairness, justice, and humanity which lay the foundation for a public health care policy worthy of the Rule of Law.

Caution

In the context of formulating this advice, artificial intelligence (AI) tools have been deployed for purposes which are purely technological and documentary, such as to organise contributions, reformulate certain passages to make them more fluent, or to integrate remarks and corrections derived from the first reading. Under no circumstances has artificial intelligence been used to direct ethical deliberation, influence normative choices, or edit the substantive conclusions of the text.

All ethical reasoning, from its foundations to its recommendations, results exclusively from discussions, interviews, and deliberations between Committee members gathered in smaller committees and plenary meetings. The full responsibility for the content of this advice, its coherence, and ethical validity lies solely with the Committee members who have approved it.

This advice has been prepared in a ‘neonatal screening’ select committee consisting of:

Co-chairpersons	Spokespersons	Members	Representative of the Office
P. Borry	F. Devaux	N. Bernheim	J. De Lepeleire
M. Surquin		F. Devaux	
		C. Herbrand	
		V. Labarque	
		C. Moulart	
		W. Pinxten	

Members of the secretariat

Beatrijs Deseyn and Sophie Bertrand

Experts interviewed by the committee

Professor Dr Béatrice Gulbis, Director of the Office of Rare Diseases, Brussels University Laboratory (H.U.B./ULB,) Co-coordinator of the European reference network EuroBloodNet

Véronique Tshiamalenge, president of the *Liège Drépasphère Association*

Diallo Fatoumata, co-founder of *Sang pour Sang Drépanocytose* (Blood for Blood – Sickle Cell Anaemia npa.)

Mimi Minsiemi Maboloko, president of the Sickle Cell Anaemia Collective Association and vice-president of the European Sickle Cell Anaemia Federation. She is a patient expert (certificate from the Patient Expert Centre). Ambassador for the gift of blood for The Red Cross

Experts who have made a written contribution

Professor Dr Maria Berghs, Health and Life Sciences, Montfort University.

This advice is available on the website: www.belgiumnationalbioethicscommittee.be/

Appendix 1: Request for Opinion

Bénédicte LINARD

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Brussels, April 24, 2024

Ref: BÉL/MEB/SéA/DéC/17.04.2024 19959

Attachment: 2

Subject: Request for opinion from the Advisory Committee on Bioethics regarding the neonatal screening programme for congenital anomalies

Dear Mr. President,

I am writing to seek the opinion of the Advisory Committee on Bioethics on a matter related to the neonatal screening programme for congenital anomalies organized in the Wallonia-Brussels Federation. This programme is based on the decree of July 17, 2002, concerning the Office of Birth and Childhood, and the decree of February 1, 2024, regarding the processing of personal data within the framework of the missions of support, preventive medicine programmes, and parental support of the Office of Birth and Childhood. The Government of the French Community's decree of January 9, 2020, on the screening of congenital anomalies in the French Community defines the implementation modalities of this programme.

The question posed is whether carriers of congenital anomalies who will not be ill should be informed of their situation. Indeed, carriers can benefit from genetic counseling, but the programme's objective is to identify and treat the ill, not to provide genetic counseling.

Currently, clinicians have divergent views on this subject, which is why the opinion of your Committee is sought, in a context where advances in genetic screening increase the ability to identify congenital anomalies.

To assist you in addressing this question, you will find attached a letter from the ONE (Office of Birth and Childhood) and a contextual note.

Thank you in advance for your attention to this matter.

Sincerely,

The Minister,
Bénédicte LINARD